FEHLING retractor Class IIa Article numbers
MBS-0, MBS-3, MBS-9, MBT-0, MBT-3, MBT-4, MBT-4C, MBT-6, MBV-7, MBV-8, MBV-9, MBZ-7, MBZ-8, MBZ-9, MFD-4, MLC-8, MMZ-1, MMZ-2, MMZ-4, MMZ-5, MRM-5, MRM-6, MSB-1, MSB-2, MSB-3, MSB-3V, MSB-4, MSB-5, MSB-6, MSB-7, MSB-8, MSE-4, MSE-5, MSE-6, MSE-9

	This medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing. Only trained medical personnel may use, reprocess or dispose of retractors and retractor components! The retractor or retractor components are only intended for short-term use.

1) Intended purpose

Retractors and retractor components, which are used invasively and for short periods in surgery, serve to separate or hold back various tissue structures, such as skin, bone, muscles and organs.

2) Indications

Surgical procedures that require the temporary spreading and holding of various tissue structures, such as skin, bones, muscles and organs, to reach the body structure requiring treatment. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the retractors or retractor blades used are of the correct size and have adequate stability.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no generally applicable contraindications for the use of retractors.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient. These include, for example, an increased risk of bone fracture in osteoporosis.

4) Possible adverse effects

The following adverse effects have been described in the medical literature during the intended use of retractors.

- Bone fractures; e.g. ribs, sternum, spinous processes, vertebrae
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses

5) Prior to use	
FEHLING INSTRUMENTS retractors and retractor components are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see Reprocessing).	
⚠	Retractors and retractor components must be handled with care during storage, transportation and cleaning! Avoid striking or applying pressure to retractors and retractor components so as not to cause any consequential damage! Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and Functional testing).

6) Reprocessing	
Reprocessing restrictions: Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use.	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	Retractors and retractor components must be handled with care during storage, transportation and cleaning! Avoid striking or applying pressure to retractors and retractor components so as not to cause any consequential damage!
⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time.
Place of use:	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately.
Storage: in accordance with § 4 of the Medical Devices Operator Ordinance (MPBetreibV)	Retractors and retractor components must be stored dry, at room temperature, clean, protected from damage and mechanical influences. It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking).
Disassembly	See 10) Disassembly:

Manual pre-cleaning	Rinse instruments under running cold mains supply water of drinking quality (<40 °C) until all visible contamination has been removed. Remove stubborn dirt with a soft brush (not a wire brush). Cavities, crevices and slits must be rinsed intensively (>10 seconds) with cold town water of drinking water quality (<40 °C) using a water pressure gun (or similar). Place the products in a combined detergent bath. Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. Ensure that all areas of the instrument come into contact with the detergent. If necessary, the moving parts of the instrument are to be moved back and forth. Validated procedures: **Manual pre-cleaning** Equipment: Basin, soft brush Detergents: neodisher® MediClean forte Mixing ratio: 0.5 – 2 % in tap water Temperature: Room temperature (23°C) Exposure time: 10 – 30 minutes During the exposure time, use appropriate brushes to remove coarse contamination. Rinse the instruments for one minute in cold deionized water
Cleaning/Disinfection	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. Compliance with the recommended concentrations, application times and temperatures is also assumed. If possible, a washer/disinfector which uses thermal disinfection is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. Always reprocess joint instruments open and/or disassembled. If applicable, loosen springs. Validated procedure: Equipment: washer-disinfector G 7835 CD (Miele) Detergent: neodisher® MediClean forte (Dr. Weigert) Preparation: • The joint instruments are to be placed in the device such, that the joints are opened and that the water can flow from the cavities and blind holes. • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. Parameters: • Pre-wash for 3 minutes with cold water (< 40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 1 % neodisher® MediClean forte in tap water at 55 °C

	• Emptying • Rinse for 2 minutes with tap water (< 40 °C) • Emptying • Rinse for 1 minute with fully deionized cold water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (> 50 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning manually	<u>Validated procedure</u> Equipment: Bandelin Sonorex Digitec Detergent: neodisher® MediClean forte (Dr. Weigert) Disinfectant: Korsolex® med AF <u>Pre-cleaning</u> • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth over the entire range of movement. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. <u>Ultrasonic cleaning</u> • Expose for 10 minutes at < 40°C with 0.5 – 3 % cleaning solution at 35kHz After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water for 10 seconds. Deionized water must be used for the final rinse. Ensure that no residues remain on the products. Rinse the instruments with deionized water for at least 30 seconds.
Disinfection manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Deionized water must be used for the final rinse. Ensure that no residues remain on the products. After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If necessary, move the moving parts in the disinfection bath. After disinfection, rinse all products thoroughly with deionized water (> 1 minute) to remove the disinfectant
Drying:	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly
Maintenance:	For instruments with movable components that are exposed to friction (e.g. joints), a high-quality water-soluble instrument spray is to be applied. Such places are additionally marked by an oil can symbol.

Checking and functional testing	Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments must be sorted out and cleaned and disinfected before being returned to the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging:	Singly: in accordance with the standard series EN 868, EN ISO 11607 and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization:	Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 132 °C 3. Holding time: 4 minutes 4. Drying time: at least 20 minutes
Storage:	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953
Disposal:	This product is made of steel. It is to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any sharp or pointed edges are protected.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing carried out achieves the desired results with the actual equipment, materials, and personnel in the reprocessing facility. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.	

⚠	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

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- Use only sterilized products of sound quality!
- Prior to inserting the retractors and retractor components, ensure that the surgical field has been prepared accordingly beforehand.
- When inserting the retractor blades, ensure that no tissue structures are unintentionally damaged (especially nerves and blood vessels)!
- Too long and too high pressure on the tissue can cause necroses, ruptures, fractures and other lesions!
- Excessive load can cause plastic deformation or breakage of the retractors and retractor components!
- Before using retractors and retractor components, ensure that their functionality is not impaired and that there is no damage!
- Before inserting retractors and retractor components, the tissue must be sufficiently prepared to improve the view of the surgical field and to avoid unnecessarily high loading!
- Prior to removing retractors and retractor components from the surgical field, ensure that the retractor arms are slowly pushed together again.

7.1) Configuration blades

The retractor has fixed blades that cannot be exchanged.

7.2) Extension module

The retractor does not have any expansion modules or exchangeable components. The attachment of other products is not recommended and is the responsibility of the user.

8) Required accessories

No accessories required.

9) Assembly

Assemble the movable retractor arm by inserting the drive lever into the box and then pushing it sideways onto the toothed rack. The drive lever must also be turned in the process. Assembly of the retractor blade is not necessary.

10) Disassembly

Completely retract the movable retractor arm from the toothed rack using the drive lever. The drive lever is now unlocked and can be pulled out of the movable retractor arm. Disassembly of the retractor blade is not necessary.

Symbols			
In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:			
Manufacturer	REF Article number	LOT Batch code	SN Serial number
Instructions for Use are to be observed	CE 0297 CE labeling	Warning	Oil can for points to be lubricated

To contact the manufacturer:	
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